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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/881,204	DOMINKO ET AL.	
	Examiner	Art Unit	
	Thai-An N Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-127* is/are pending in the application.

4a) Of the above claim(s) *69,86-97, 101-119, 125* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48-68,70-85,98-100,120-124,126 and 127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/24/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' Amendment, filed 11/24/03, has been entered. Claims 48-72, 74-90, 92-119 have been amended. Claims 120-127 have been added. Claims 48-127 are pending. Claims 69, 86-97, 101-119 and 125 are withdrawn. Claims 48-68, 70-85, 98-100, 120-124, 126 and 127 are under current examination.

Election/Restrictions

Applicants' addition of claim 125 has not been considered because it does not fall within the groups defined in the Restriction Requirement, mailed 10/03/02. It has been determined that claim 125, directed to methods of reprogramming, wherein the reprogramming is facilitated by use of chemically or biologically derived agents known to cause gene reactivation, falls within Group VI of the original Restriction requirement. Group VI is directed to methods of generating a pluripotent mammalian cell wherein already established populations of hybrid-derived cells are cultured in the presence of compounds or factors known to induce gene transcription. Accordingly, claim 125 has been withdrawn from examination.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 99 and 100 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to pluripotent cells and populations of pluripotent cells generated by nuclear transfer. This is non-statutory because these products read on pluripotent cells *in vivo* [such as primordial germ cells, or hematopoietic stem cells, for example], or embryos/zygotes. The recitation of "isolated" would overcome this rejection.

The claims are further rejected because encompasses any pluripotent cell, the scope of which encompasses a human being [for example, a human embryo/zygote], which is non-statutory subject matter. As such, the recitation of the limitation "non-human" would be remedial. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-68, 70-85, 98-100, 120-124, 126 and 127 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to methods for generating pluripotent mammalian cells by preparing more than one cytoplast fragment from a mammalian oocytes or fertilized zygote, obtaining a nuclear donor cell or karyoplast taken from a mammal, and combining the cytoplast fragment with the nuclear donor cell or karyoplast to produce a pluripotent mammalian cell.

The specification teaches methods of nuclear transfer [NT] to produce pluripotent cells. The specification teaches that nuclear donors from a variety of species could be used in combination with enucleated bovine oocytes. Particularly, the specification teaches that the pluripotent cells of the invention would be produced by using cytoplast fragments obtained from either whole enucleated oocytes, or whole, enucleated zygotes. The cytoplast fragments are then fused with nuclear donors of the same species or another species to form a hybrid cell, which is maintained in the undifferentiated state such that the nuclear donor is reprogrammed. See p. 8, [0018]. The specification teaches the production of porcine-porcine hybrid cells utilizing porcine cytoplasts. Porcine oocytes arrested at metaphase II of the meiotic cycle were collected, the zona pellucidae removed and the oocytes were then incubated in Pronase. The optimal cytoplast size was obtained by vortexing the oocytes. Porcine fibroblasts were collected to be used as nuclear donors. The cells and oocytes were then fused and the hybrid cells were then analyzed. See Example 1. The specification teaches the producing of porcine-rabbit hybrids, wherein rabbit oocytes, arrested at MII of the meiotic cycle were

isolated and micromanipulated. These oocytes were then fused with porcine fibroblasts. See Example 2. The specification teaches the maturation of bovine cumulus oocytes complexes, maturing the oocytes, removal of the zona and then incubation with cytochalasin B. These oocytes were then fragmented by vortexing and cytoplast fragments were collected. Enucleated cytoplasts were then fused to porcine fetal fibroblasts and the hybrid cells cultured overnight but not activated. The cells were then analyzed and then activated in the presence of BrdU to test for DNA synthesis. The cells were then cultured for 7 days, where they aggregated and formed an embryoid body or mass that possibly indicated the ability to differentiate. See Example 3 and Figure 5. The specification teaches that cytoplast fragments from bovine oocytes were then prepared and analyzed. See Example 4. Bovine cytoplasts were fused with bovine fetal fibroblasts. The resulting hybrid cells were cultured and myocardial-like cells were observed to be beating in a colony of the cells. See Example 5.

The instant specification fails to enable the claimed invention because the claims are directed to methods for generating pluripotent mammalian cells by NT. The specification fails to provide teachings or guidance to show that the resulting hybrid cells are, indeed, pluripotent. The specification defines *pluripotent* as, "A cell that is capable, through its progeny, of giving rise to all cell types which comprise the adult animal including the germ cells." See p. 14, ¶ [0049]. The working examples provided by the specification fail to show pluripotency in the

resulting hybrid cells. Example 3, which describes the production of porcine-bovine hybrid cells, states that cell colonies that appeared in culture "aggregated into an embryoid body or mass" and then speculates that these cells have a potential to differentiate. The cells of Example 3 were then described to have a different morphologies, which "resemble " embryonic stem cells. Further, Example 5 teaches the generation of myocardial-like cells, which were observed to be beating. The specification fails to teach specific characterization of the hybrid cells such that one of skill in the art would be able to identify them as *pluripotent*. Particularly, the specification teaches that cells such as ES cells are considered pluripotent; however, it is art-recognized that ES cells have specific, defined characteristics to identify them as pluripotent. For example, Thomson *et al.* [Reference AT 21 of Applicants' IDS, filed Oct. 18, 2002] teach the isolation of a pluripotent, primate embryonic stem cell line. They teach that these cells remain undifferentiated in culture in continuous passage, maintain a normal karyotype, express appropriate cell markers (alkaline phosphatase, SSEA-3, SSEA-4, TRA-160-, TRA-1-81] and, when injected into SCID mice, they consistently differentiate into derivatives of all three germ layers. See *Abstract* and p. 7845-7846. The instant specification fails to provide characterization of the claimed cells, other than description of a morphology that resembles ES cells, and the generation of myocardial-like cells, which were observed to beat. This is not sufficient to demonstrate that the claimed cells are capable of, for example, give rise to all cell types, as required by both the instant specification's

definition of pluripotent, and the art-recognized definition of the term. The specification fails to teach analysis of the hybrid cells to show that they are capable of remaining undifferentiated in culture, maintain a normal karyotype and express the appropriate cell markers associated with pluripotency.

Furthermore, with regard to the breadth of the claims which encompass methods of NT utilizing any mammalian oocytes with any nuclear donor, it is noted that methods of NT require specific methods steps to enable them because the unpredictabilities associated with NT. For example, successful NT requires both ideal recipient oocytes and donor cells, proper activation and embryo culture and implantation into a suitable host animal to produce an animal. The unpredictable state of the art of NT is supported by Campbell [**Cloning & Stem Cells**, 3(4):201-208 (2001)] state that, "Successful development [of the NT unit] is dependent upon numerous factors, including type of recipient cell, source of recipient cell, method of reconstruction, activation, embryo culture, donor cell type, and donor and recipient cell cycle stages." See *Abstract.* The specification teaches that the oocytes used in the working examples are MII oocytes, however, the breadth of the claims are to oocytes from any stage of development. Campbell teaches that metaphase II [MII] oocytes are considered the cytoplast of choice because the genetic material is arranged upon the meiotic spindle and easily removed [see p. 202, 2nd column, 1st ¶], further, following introduction of the donor somatic cell into an enucleated oocyte, activation must occur to induce further development and the timing of this

activation in relation to NT has been implicated in the ability of the NT unit to develop further [see p. 203, 2nd col.]. Fulka *et al.* [**Theriogenology**, 55(6):1373-1380 (2001)] state that the three basic types of cytoplasts 1) enucleated metaphase II oocytes that are used immediately for NT, 2) MII oocytes that are enucleated and aged in culture to be used in NT and 3) oocytes that are first activated and then enucleated in telophase II before use in NT. See p. 1374. Accordingly, the state of the art supports that oocytes in MII or oocytes in telophase II be used for successful NT.

The claims fail to provide a step of activating the resulting NT unit; thus, without further development of the NT unit, it would not be possible to generate a pluripotent cell. Indeed, the step of activating the NT unit is essential; Dinnyés *et al.* [**Cloning & Stem Cells**, 4(1): 81-90 (2002)] state that, "In NT, the lack of sperm-induced fertilization steps necessitate the application of an artificial activation in order to trigger further development." See p. 83, 2nd column, last ¶. Dinnyés state that, "NT is a complex procedure, and each step affects the overall efficiency. The unpredictability of the technology due to biological variation of the recipient oocytes and donor cells is difficult to control. Therefore, standardization of steps is important in order to obtain consistent results. Improvements in technical steps may have lasting effects on the development of the fetus." See p. 83, 1st column, 2nd full ¶. The instant claims fail to provide steps of activation or further culture of the NT unit

The breadth of the claimed invention encompasses the cloning human cells [see claim 83, in particular]. These embodiments are not enabling because of the art-recognized inability to clone primates. Vogel [**Science**, 300:226-227 (2003)] state that Rhesus monkey NT-generated embryos seemed normal at their early stages but were unable to develop further when implanted into a surrogate mother. This was because the cells had the wrong number of chromosomes, and that this aneuploidy resulted in the abortion of the fetus. This was found to also be the case with human NT embryos. See p. 225. Simerly *et al.* [**Science**, 300:297 (2003)] state that, "Primate NT appears to be challenged by stricter molecular requirements than in other animals ... With current approaches, NT to produce embryonic stem cells in nonhuman primates may prove difficult – and reproductive cloning unachievable." See p. 297, 3rd column, last sentence. As the state of the art evidences that NT in primates is unpredictable, and the instant specification fails to provide teachings to show that primate NT using the claimed methods would result in pluripotent mammalian cells, it would have required undue experimentation for one of skill in the art to make and use the claimed invention.

Accordingly, the Examiner has clearly provided evidence for the unpredictability of the NT art, as such specific guidance must be provided by the specification. However, the instant specification fails to provide teachings or guidance to overcome these unpredictabilities. One of skill in the art could not rely on the state of the art, because it is replete with teachings to show NT's

unpredictability for any donor cell and any recipient oocyte, as broadly claimed. Accordingly, in view of the undeveloped and unpredictable state of the art with regard to NT, it would have required undue experimentation for one of skill in the art to carry out the claimed methods.

Claim Rejections - 35 USC § 112

The prior rejections under 35 USC 112, 2nd ¶ of claims 62-65, 77 and 81 are withdrawn in view of Applicants' amendments to the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The prior rejection of claims 48, 54-67, 70-79, 81, 82, 84, 85, 98 is withdrawn, however, the prior rejection of claims 99 and 100 under 35 U.S.C. 102(b) as being anticipated by Campbell *et al.* [WO 97/07668, published 6 March 1997] is maintained for reasons of record.

Applicants state that the amended claims are now directed to preparation of "more than one" cytoplast fragment from a mammalian oocyte, and combining the

cytoplast fragment with a nuclear donor. Applicants argue that Campbell specifically indicates that techniques should be employed to increase the amount of cytoplasm in the oocyte, and point to where it is stated that the enucleation of the oocyte should be done with minimum disruption to the cytoplasm. Applicants argue that Campbell teaches away from the claimed invention because they do not teach NT methods for the production of pluripotent or reprogrammed cells, but methods for the productions of reconstituted animal embryos.

Applicants' arguments/amendments to the claims are found to be persuasive with regard to the claimed methods because the prior art fails to teach the preparation of more than one cytoplast fragment, as required by the amended claims. However, the prior rejection is maintained for the product claims [claims 99 and 100] because the claims are product-by-process claims.

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See In re Ludtke, supra. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA

1036, 459 F.2d 531, 173 USPQ 685 (1972). Further, see MPEP §2113, "Even though product-by process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

As such, the claims are properly interpreted as pluripotent cells. Campbell's teaching of reconstituting animal embryos by NT methods anticipate the demonstration of a reconstituted animal embryo shows the pluripotency of the cells produced by NT. Furthermore, because Campbell teaches that the NT donor cells can be differentiated cells, the reconstitution of an animal embryo [production of an NT unit], and the subsequent further development of the NT unit into an animal demonstrates the reprogramming of the differentiated cell nucleus. Thus, contrary to Applicant's assertion, Campbell does not teach away from the claimed invention. Accordingly, Campbell anticipates the claimed invention.

The prior rejection of claims 48, 54, 55, 58, 59, 61-64, 66, 70, 71, 73, 74, 76-82, and 98 is *withdrawn.* The prior rejection of claims 99 and 100 under 35 U.S.C. 102(b) as being anticipated by Campbell *et al.* is *maintained* for reasons of record.

As *supra*, Applicants argue that Campbell's methods of NT fail to teach the claimed invention because they utilize NT to produce reconstituted embryos to examine the influence of the cell cycle stage of both the donor nucleus and the recipient cytoplasm upon the morphology and DNA synthesis potential of the donor nucleus, and the claims as amended are directed to methods for the production of pluripotent or reprogrammed cells.

Applicants' arguments/amendments are found persuasive with regard to the method claims because the prior art fails to teach the preparation of "more than one cytoplast fragment" as required by the amended claims. However, the prior rejection is maintained for the product claims [claims 99 and 100] because the claims are product-by-process claims [see *supra*]. Thus, it is maintained that Campbell anticipates the claimed invention because they teach methods of NT for the reconstruction of animal embryos. The production of the NT-embryo and subsequent development demonstrate the pluripotency of the reprogrammed cell donor nuclei. Accordingly, it is maintained that Campbell teach the claimed invention.

The prior rejection of claims 48, 54-59, 61-67, 70, 71, 73, 75-82, 84, 85 and 98 is *withdrawn*. The prior rejection of claims 99 and 100 under 35 U.S.C. 102(b) as being anticipated by Wolf *et al.* [cited in the prior Office action] is maintained for reasons of record.

Applicants argue that Wolf's methods of NT fail to teach the claimed invention because they do not teach the generation of more than one cytoplast fragment, that they teach away from the instant claims because they teach using a high karyoplast-cytoplast volume ratio may interfere with development of bovine NT embryos. Applicants further argue that Wolf do not teach the production of pluripotent or reprogrammed cells made by the claimed methods.

Applicants' arguments are found to be persuasive with regard to the method claims, because the prior art fails to teach the recitation of "more than one cytoplast fragment" as required by the claims. However, the prior rejection is maintained for the product claims [claims 99 and 100] because the claims are product-by-process claims [see *supra*]. Thus, it is maintained that Wolf anticipates the claimed invention because they teach methods of NT for the reconstruction of animal embryos. The production of the NT-embryo and subsequent development of the embryos to produce animals, demonstrate the pluripotency of the reprogrammed cell donor nuclei. Accordingly, Wolf anticipate the claimed invention.

The prior rejection of claims 48, 54-57, 61-64, 66, 67, 70-74, 76-79, 81, 82 and 98-100 under 35 U.S.C. 102(b) as being anticipated by Susko-Parrish *et al.* [**cited in the prior Office action**] is withdrawn. Applicants' arguments and/or amendments to the claims is found to be persuasive because Susko-Parrish do not teach utilizing "more than one" cytoplast fragment for NT methods.

The prior rejection of claims 48, 54-57, 61-64, 66-68, 70-73, 75-79, 81, 82 and 98 is *withdrawn*. The prior rejection of claims 99 and 100 under 35 U.S.C. 102(b) as being anticipated by Sims *et al.* [cited in the prior Office action] is *maintained*.

Applicants argue that Sims do not teach the claimed invention because they teach non-disruptive enucleation of an oocyte and not the cytoplast fragments as claimed. See pp. 16-17, bridging ¶ of the Response. Applicants further argue that the Sims patent does not teach the production of pluripotent or reprogrammed cells because they teach embryonic single-celled clones that are transplanted into the uteri of suitable animals and grown to term.

Applicants' arguments are found to be persuasive with regard to the amended method claims because the cited art fails to teach the recitation of "more than one" cytoplast fragment, as required by the claims. However, the prior rejection is maintained for the product claims [claims 99 and 100] because the claims are product-by-process claims [see *supra*]. Thus, it is maintained that Sims anticipates the claimed invention because they teach methods of NT for the reconstruction of animal embryos. The production of the NT-embryo and subsequent development of the embryos to produce animals, demonstrate the pluripotency of the reprogrammed cell donor nuclei. This further supports the reprogramming of the donor cell nucleus. Thus, Sims anticipates the claimed invention.

The prior rejection of claims 48, 54-60, 62-67, 70, 71, 75-78, 81-85 and 98 is *withdrawn.* The rejection of claims 99 and100 under 35 U.S.C. 102(b) as being anticipated by Robl *et al.* [cited in the prior Office action] is *maintained.*

Applicants argue that Robl does not teach the claimed invention because they do not teach further modification of the enucleated oocyte, and do not teach the preparation of more than one cytoplast fragment from the oocyte. See p. 17 of the Response.

Applicants' arguments and/or amendments are found to be persuasive with regard to the amended claims because the cited prior art does not teach the limitation of, "more than one" cytoplast fragment, as required by the claims. However, the prior rejection is maintained for the product claims [claims 99 and 100] because the claims are product-by-process claims [see *supra*]. Thus, it is maintained that Robl anticipates the claimed invention because they teach methods of NT for the generation of embryonic stem cell lines. The production of the embryonic cell lines, which are pluripotent, would demonstrate the reprogramming of the donor cell nuclei by NT. Accordingly, Accordingly, Robl *et al.* anticipate the claimed invention.

The prior rejection of claims 47-57, 60-64, 66, 67, 70-74, 77, 78, 81, 82 and 98-100, newly added claims 123, 124, and 127 is *maintained* under 35 U.S.C. 102(b) as being anticipated by Peura [cited in the prior Office action] is *for* reasons of record.

Applicants argue that Pleura teaches the desirability of increasing, rather than decreasing, the levels of cytoplasm contributed by the donor oocytes, and that Pleura teach that multiple cytoplasts be fused in order to enhance the volume of cytoplasm which is in contrast to the claims of the instant invention, which recite the use of cytoplast fragments in order to generate pluripotent or reprogrammed cells. Applicants conclude that Pleura does not anticipate the claimed invention because they do not teach preparing more than one cytoplast fragment from a mammalian oocyte in an NT method to produce a pluripotent or reprogrammed mammalian cell. See p. 18 of the Response.

Applicants' arguments are not persuasive. Peura's methods are directed to producing reconstituted embryos, and they particularly teach a method of, "[I]ncreasing cytoplasmic volume in an embryonic cell said method including providing at least two cytoplast prepared by a method of enucleating an oocyte, providing an embryonic cell; and fusing said cytoplasts with embryonic cell." See p. 10, lines 18-28, emphasis added. Thus, Peura clearly teach the claimed invention because they state that at least two cytoplasts can be produced by enucleating an oocyte, as required by the claims. Applicants' arguments that because Peura teach increasing, rather than decreasing the levels of cytoplasm contributed by donor

oocytes in NT methods show that Peura do not teach the claimed method are not persuasive. The claims merely require the teaching of the preparation of more than one cytoplast fragment from an mammalian oocyte for use in NT. The claims do not require a decrease or increase in the total amount of cytoplasm contributed by the cytoplast. Furthermore, with regard to Applicants' arguments that Peura do not teach methods for the production of pluripotent or reprogrammed cells, Peura teaches production of NT-generated embryos which can then be allowed to further develop into animals. See p. 12, lines 15-18. The generation of an animal provides evidence that the NT unit is both reprogrammed and pluripotent. Accordingly, it is maintained that Pleura anticipate the claimed invention.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1632

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the Examiner be unavailable, inquiries should be directed to Amy Nelson, Acting SPE of Art Unit 1632, at (571) 272-0804. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

Thaian N. Ton
Patent Examiner
Group 1632